Kaiser Foundation Health Plan
Program Offices

October 24, 2016

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave. SW
Washington, DC 20201

Submitted electronically on *www.HealthIT.gov*

RE: ***ONC Draft 2017 Interoperability Standards Advisory***

Kaiser Permanente offers the following comments on the **Draft 2017 Interoperability Standards Advisory ("2017 Advisory")**, posted August 22, 2016 at the Office of the National Coordinator for Health Information Technology ("ONC") webpage.[1]

The Kaiser Permanente Medical Care Program is the largest private integrated healthcare delivery system in the U.S., with over 11.6 million members in eight states and the District of Columbia.[2] Kaiser Permanente is committed to providing high-quality, affordable health care services and improving the health of our members and the communities Kaiser Permanente serves.

Kaiser Permanente appreciates the opportunity to provide our feedback.

GENERAL COMMENTS

Kaiser Permanente supports proposed improvements to the 2017 Advisory, including changes in organization; the planned transition from a stand-alone "paper-like" document report to a web-based interactive resource as well as maintaining a single complete document version; the addition of an "in development" class for the Standards Process Maturity measure; discontinuation of the "best available" label; and the addition of a separate "emerging standards and implementation specifications" section for each item.

[1] https://www.healthit.gov/standards-advisory/draft-2017

[2]Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 38 hospitals and over 600 other clinical facilities; and the Permanente Medical Groups, independent physician group practices that contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente's members

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Although the web version of the 2017 Advisory is very useful when trying to locate a specific topic/item, it is not as helpful when reviewing the content in its entirety. Kaiser Permanente supports ONC plans to maintain both formats.

The draft states the 2017 Advisory remains focused on "clinical health information technology interoperability." Kaiser Permanente remains concerned about excluding certain standards the primary use of which may be "administrative" in nature but which also can be critically important in clinical decision-making. Specifically, the exclusion of the *Claim Attachment* transaction should be revisited.

The 2017 Advisory represents the model approach ONC intends to use to coordinate the identification, assessment, and public awareness of interoperability standards and implementation specifications for industry use. The 2017 Advisory would facilitate the interactive process for defining standards for future adoption, implementation, and use. Thus, it should be interpreted as a non-binding indication of ONC's assessment of recommended standards and implementation specifications. In this process, ONC should prioritize selection of standards and specifications developed by organizations and methods that are properly accredited or otherwise strictly qualified.

Available Specifications

Many standards and implementation specifications in all three sections (*Code Sets, Content, Services*) in the 2017 Advisory are in: 1) Final Status; 2) Production Level; 3) Widely Adopted State; and 4) Mandated/Regulated. One of the primary purposes of the 2017 Advisory is to identify promising standards that are in earlier stages of development with significant potential to be finalized, adopted and widely used.

Therefore, Kaiser Permanente recommends the 2017 Advisory should concentrate on those promising standards with significant potential to be finalized, moved into production, and widely adopted soon as balloted standards, rather than fully mature standards that are already in production, widely implemented, specified in regulations, or likely to be published in a separate document. From our analysis, the document lists 70 federally mandated and 89 unmandated final standards versus the 9 federally mandated and 54 unmandated balloted standards; the number of final standards is almost triple the number of balloted standards. This imbalance undermines the forward-looking intent of the 2017 Advisory and raises the question of whether it is "advisory" or "regulatory."

Beyond Meaningful Use

ONC's rationale for issuing the 2017 Advisory remains unclear. Kaiser Permanente strongly recommends ONC provide information regarding whether a 2017 Edition Certification Criteria regulation will be published.

Instead of helping the health care industry by providing its assessment of standards, ONC creates some unnecessary confusion about selection, implementation, and use of standards, given current regulations for the Standards and Certification program and recommendations provided by the

ONC Standards Committee and others. Kaiser Permanente fails to see how the 2017 Advisory fits into the broader context of Health IT.

ONC should be more explicit about the intended purpose and application of the 2017 Advisory as sub-regulatory guidance, without the force of law. ONC should clarify distinctions between HIT standards-setting policies and programs including the 2017 Advisory; the CMS MU program regulations or related CMS regulations; the ONC 2015 Health IT Certification regulation; publications of Standards Development Organizations ("SDO"), and other federal standards-setting initiatives, including ONC's Standards and Interoperability ("S&I") program or National Information Exchange Model ("NIEM").

Updating the Advisory

Unlike previous versions of the Advisories, ONC does not propose to provide updated material on an annual basis. An annual process would raise serious questions and concerns. Specifically, ONC should address what timing should be expected in the future (e.g., whether the assessment process and Advisories will continue, or whether a different timeframe would be more consistent with industry capabilities to adopt and implement, etc.). ONC should establish an open, transparent, and balanced process to provide input to any future Advisory; part of this should be a decision about whether to publish Advisories under a regulatory or sub-regulatory process, or through a wholly new mechanism to be created by ONC to gather input.

Interactive Ability

ONC highlights several changes that have been applied to the 2017 Advisory. Kaiser Permanente supports the transition from a stand-alone, fixed resource to one that also serves as an interactive, web-enabled resource. ONC should clarify how the outcomes of the *Interoperability Proving Ground* will be incorporated into updated Advisories. Kaiser Permanente recommends that ONC publish and incorporate any results, lessons learned, outcomes, or other benefits obtained from this and other efforts in the *Specifications and Implementation* section.

Scope

It appears that listing more than one standard or implementation specification is intended to prompt industry dialogue about whether one standard or implementation specification is necessary or whether the industry can efficiently interoperate more than one. However, ONC provides no detail about how and when such dialogue would occur; how it would be governed, which stakeholders would be involved, or what decision-making process would be used to revise and finalize the list. Open and transparent decision-making is required and the various interests of relevant stakeholder groups (such as clinicians, vendors, payers, patients, researchers, and Government) must be balanced in the process.

The 2017 Advisory does not distinguish between standards from American National Standards Institute ("ANSI") accredited SDOs, or similarly recognized international standards (e.g., International Standards Organization ("ISO")), versus unaccredited "standards" including guidance from sources that may not follow the requirements of voluntary consensus standards

bodies as set forth in the National Technology Transfer and Advancement Act of 1995 (PL 104-113) and OMB circular A-119 as revised in 2016. Kaiser Permanente strongly recommends that ONC prioritize standards from accredited SDOs when both accredited and unaccredited sources exist, and that only qualifying voluntary consensus standards published by organizations adhering to the ANSI Essential Requirements of 2016 or the Decisions and Recommendations of the World Trade Organization (WTO) Committee on Technical Barriers to Trade (TBT) should be recommended as standards or used in relevant conformity assessment activities.

Standards and Implementation Specifications

The 2016 Advisory began to identify the need for vocabulary harmonization across standards. Kaiser Permanente supports vocabulary harmonization of clinical records using SNOMED CT and LOINC as the primary reference standards. For administrative purposes, those clinical standards must be translated into ICD, CPT, or HCPCS codes when required. Standards intended solely for secondary use data collection or other non-clinical-care purposes should not become mandatory in EHR technology. For example, the Clinical Data Interchange Standards Consortium ("CDISC") standards use vocabularies that are not in sync with the HL7 standards or implementation guides used in clinical records, such as the HL7 Consolidated-Clinical Document Architecture ("C-CDA").

The path to semantic interoperability requires that vocabularies across all standards and implementation guides should be able to express identical concepts. The 2017 iteration of the Advisory should include vocabulary harmonization to SNOMED CT and LOINC reference standards as a criterion in support of a transition to their widespread use as the basis for primary clinical data capture. During the transition and convergence, the industry could indicate the level of harmonization such as the "Identified standards and implementation specifications" characteristics, while ONC could work with the National Library of Medicine ("NLM") and the respective SDOs to harmonize variant vocabularies.

Future Considerations

To promote the benefits of patient-generated health data ("PGHD") and consumer devices, ONC should consider the interoperability of EHR systems with mobile health platforms, including consumer grade devices, as well as FDA registered or regulated remote devices. There is relatively little information in the 2017 Advisory regarding mobile devices, mobile medical apps, and interoperability. Kaiser Permanente recommends ONC prominently highlights this area.

Despite a proliferation of apps, proprietary exchange mechanisms result in little interoperability across mobile apps and devices. The technical promise of emerging standards such as HL7 FHIR may fade through a lack of authoritative governance and coordination over the development, management, and use of these standards. The complexity, abundance, and variety of use case scenarios for mobile devices and PGHD argues for strict adherence to a limited set of national standards to avoid overloading certified HIT with conflicting demands for software development and deployment. Again, Kaiser Permanente recommends focusing on the use of SNOMED CT and LOINC as central reference standards for semantic interoperability. At the same time, the

impact on EHR clinician user workflows should be considered carefully before including consumer-oriented standards in a future Advisory.

Emergency Response

Representatives from OASIS (www.oasis-open.org) have approached HL7 and the members of the Patient Administration group (including Kaiser Permanente) to synchronize efforts to establish standards around *Emergency Management Patient Tracking* ("EXDL-TEP") and *Emergency Data Exchange Language Hospital Availability Exchange* ("EXDL-HAVE").

Kaiser Permanente has explored how HL7 ADT messages might receive or otherwise contain information related to a crisis (a natural disaster or other catastrophe), such as data gathered in the field from a mobile device. At least one of the ADT messages is now jointly endorsed under a Memorandum of Understanding ("MOU") between HL7 and OASIS and could be content for any section addressing Emergency Response.

ISA Structure

The 2017 Advisory provides some very thorough and descriptive characteristics of the six sections for additional context; however, information is missing that would help readers gain a better understanding of all characteristics presented. ONC should include information for these additional characteristics:

- Limitations, Dependencies, and Preconditions for Consideration
- Section I: Applicable Value Set(s) and Starter Set(s)
- Sections II & III: Applicable Security Patterns for Consideration

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications

- Section I-E: Health Care Provider (Representing Provider Role in Care Setting)
  - Kaiser Permanente recommends removing "HL7 Participation Function", restrict to the following SNOMED-CT® concepts and their children: 429577009 - Patient Advocate; 223366009 - Healthcare professional; 394730007 - Healthcare related organization

- Section I-G: Immunizations
  - RxNorm is listed in Value Sets, but is not included in Standards. Kaiser Permanente recommends adding this as a "Standard."
  - Kaiser Permanente recommends including MVX as a "Standard" as it should also be included in Standards to complement CVX.

- Section I-H: Industry and Occupations
  - In the Limitations, Dependencies, and Preconditions for Consideration box, Kaiser Permanente recommends the following changes/corrections:
    1. The text "Industry and Occupation Computerized Coding System" should be replaced with "CDC_Census Coding System" which is being recommended by NIOSH and aligns with job classifications. Federal agencies are required to use standard classifications (such as North American Industry Classification System) and the

Standard Occupation Classification System. Kaiser Permanente agrees that using standardized code sets increases interoperability throughout the healthcare community and recommends ONC replace NIOCCS with CDC_Census Coding System.

2. NUCC and its Health Care Taxonomy code standard is not an appropriate reference, since that code set is a classification of health profession specialties (medical, nursing, etc.) and not an occupation classification system. Kaiser Permanente recommends deleting this reference.
3. Lastly, Kaiser Permanente recommends ONC should explicitly note the international classifications of occupation are not as granular as the one being referenced by NIOSH (CDC_ensus) for use in the US.

- Section I-J: Medications
  - SNOMED CT is identified as a Value Set; therefore, Kaiser Permanente strongly recommends adding this to the Standards list

- Section I-R: Sexual Orientation and Gender Identity (Interoperability Need: Representing Patient Sex (At Birth))
  - For clarity, Kaiser Permanente recommends ONC change the standard for values to "HL7 Version 3" and leave the additional clarification in the Applicable Values Set(s) text.
  - Because there is no need to indicate Gender, unknown, etc. Kaiser Permanente recommends the HL7 Version 3 remains.

- Section I-U: Unique Device Identification
  - The HL7 Harmonization Pattern for Unique Device Identifiers is only applicable to HL7 standards (v2, v3, CDA, FHIR), which is probably sufficient for this Interoperability Need, however, Kaiser Permanente recommends UDI be use in other scenarios (e.g., ePrescribing and other device orders) and should be added to the Limitations box.

- Section I-V: Vital Signs
  - The Vital Sign observations are mostly numeric therefore, Kaiser Permanente recommends UCUM be listed in the "Standards" section as the standard for units of measure for the representation of observed values.

Section II: Content/Structure Standards and Implementation Specifications

- Section II-A: Admission, Discharge, and Transfer
  - Within an organization (i.e., an inpatient facility with in-house pharmacy), ADT messages to the servicing pharmacy would likely be HL7 v2.x ADT messaging rather than NCPDP SCRIPT CENSUS. "External" pharmacies, such as pharmacies servicing long term care facilities, use NCPDP SCRIPT CENSUS and should continue to do so. When to use HL7 or NCPDP in these cases should be left up to the organization, based on the business environment. Kaiser Permanente recommends supporting both, having HL7 v2.x ADT and NCPDP SCRIPT CENSUS in the "Standard" section.
  - X12-278 is also used to provide notifications of about a patient between separate institutions, therefore, Kaiser Permanente recommends including this as well.

- Section II-D: Clinical Quality Measurement:
  - *HQMF:* Kaiser Permanente recommends that Implementation Maturity should be "Production."
  - *FHIR Profile: Quality:* Kaiser Permanente recommends naming it in this location and current content; however, Kaiser Permanente requests this document be renamed from "FHIR Profile: Quality" to "FHIR Profile: Quality (QI-Core)." Also, the URL for QI-Core should be corrected.
  - *CQL:* Kaiser Permanente recommends naming it in this location. The URL should be corrected and take the user to the CQL document (not the STU comment site).
  - *QDM-based HQMF:* Kaiser Permanente recommends identifying this in the location listed, however, the name should be modified to "Release 1.4 DSTU 4 (based on HQMF 2.1)." The "Federally required" should be changed to "yes" as this is required by a federal program (Medicare) and the definition of this column includes "…adopted in regulations, referenced as a federal program requirement, or referenced in a federal procurement…." Kaiser Permanente also recommends correcting the URL so that it references the appropriate information.
  - *Emerging – CQL-based HQMF:* Kaiser Permanente recommends naming it in this location and the name should be "Release 1 DSTU 1." The URL currently takes the user to the HL7 Standards Master Grid, and not to the CQL-based HQMF document. Kaiser Permanente recommends correcting the URL.
  - *Emerging – CQF on FHIR:* Kaiser Permanente recommends naming it in this location and with the content provided.
  - *Addition:* Kaiser Permanente recommends adding FluentPath as an emerging standard, in development, pilot status, one-dot adoption, not required, free of charge, no test.

- Section II-E: Clinical Quality Reporting
  - *CDA:* Kaiser Permanente recommends naming it in this location and with the content provided.
  - *QRDA Cat III:* Kaiser Permanente recommends naming it in this location. The ballot reference name should be corrected to "HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture – Category III (QRDA III) Release 1 DSTU Release 1."
  - *Emerging - QRDA Cat III:* Kaiser Permanente recommends naming it in this location and with the content provided. The name should be changed to "DSTU Release 3" rather than "DSTU Release 2." This also should be listed not federally required as this is still under development. Kaiser Permanente expects this will be called "QRDA III Release 1.1" once complete and therefore, Kaiser Permanente recommends ONC change the naming convention.

- Section II-G: Drug Formulary & Benefits
  - Kaiser Permanente recommends including the NCPDP Real Time Prescription Benefit Inquiry in the Standards list as an "Emerging Standard."

- Section II-H: Electronic Prescribing
  - Interoperability Need: A Prescriber's Ability to Create a New Prescription to Electronically Send to a Pharmacy - Kaiser Permanente recommends the following bullet be deleted "• Allows the pharmacist to notify the prescriber about the status…" This is

not part of the NEWRX message which applies to the Interoperability Need (see "Fill Status", below).
  - Interoperability Need: Allows Prescriber to Respond to a Prior Authorization for a Medication Electronically to the Payer/Processor – Kaiser Permanente recommends the following information be added to the Limitations and Applicable Security portion "A Prescriber's Ability to Obtain a Patient's Medication History."
  - Interoperability Need: Prior Authorization Cancel Request - Kaiser Permanente recommends the following information be added to the Limitations and Applicable Security portion "A Prescriber's Ability to Obtain a Patient's Medication History."

- Section II-O: Public Health Reporting
  - Kaiser Permanente strongly recommends the 2017 Advisory include the following standards for vital statistics in a new sub-section "Vital Statistic Reporting" within Section II-O "Public Health Reporting" under Section II – Content/Structure Standards and Implementation Specifications:
    - HL7 Version 2.5.1 Implementation Guide: Birth and Fetal Death Reporting, Release 1.1 (US Realm)
    - HL7 Version 3 CDA R2 Implementation Guide: Birth and Fetal Death Reporting, Release 1 (US Realm)
    - Integrating the Healthcare Enterprise (IHE) Birth and Fetal Death Reporting – Enhanced (BFDR-E) supplement
    - HL7 Version 2.6 Implementation Guide: Vital Records Death Reporting, R2 (US Realm)
    - HL7 Version 3 CDA R2 IG: Reporting Death Info from the EHR to Vital Records, R1 (US Realm)
    - Integrating the Healthcare Enterprise (IHE) Vital Records Death Reporting (VRDR) supplement
  - Kaiser Permanente recommends all references to FHIR STU 3 be updated to balloted status.

- Section II-P: Representing clinical health information as a "resource"
  - Kaiser Permanente recommends only applying the term "Resource" to clinical health information when used specifically in a scenario that is using the FHIR standards. This concept makes sense in the context of using FHIR resources in a RESTful context; that is, using resources that live on a FHIR compliant server. In theory, FHIR resources also support other methods of information exchange in styles like transactional message exchange (notionally like V2.x messaging), exchange of a complete, static "documentation" of a patient stay in a hospital (think Clinical Document Architecture) and, finally, in use as units of exchange in a service oriented architecture.

- Section II-S: Summary care record
  - Interoperability Need: Support a Transition of Care or Referral to Another Health Care Provider.

    The HL7 Privacy Consent Directive CDA IG allows for computable consent directives utilizing structured privacy and security vocabulary in such a way that trading partners

can readily exchange such patient preferences successfully. This approach provides a logical pathway for passing consent directives among trading partners and deserves due consideration going forward. Kaiser Permanente supports this as a means of facilitating transitions of care and referrals to other health care providers.

Section III: Standards and Implementation Specifications for Services

- III-G: Query
  - Kaiser Permanente seeks any updates for activity specific to this item for 2016. For example, "• The MHD supplement is based on FHIR DSTU1.1. The IHE MHD committee is currently working to update the MHD profile and planning to release it to implementers in first quarter calendar year 2016."

Section IV: Questions and Requests for Stakeholder Feedback

General

1. For each standard and implementation specification there are six assessment characteristics, for which detailed information has been received and integrated. However, some gaps remain. Please help complete information that is missing or noted "feedback requested". Additionally, assessing the adoption and maturity of standards is an ongoing process, so please continue to provide feedback if you believe something has changed or is not correct.
   No comment.

2. The table beneath the standards and implementation specifications includes limitations, dependencies, and preconditions. Given the enhancements made, please comment on accuracy and completeness and where information gaps remain, forward applicable content.
   No comment.

3. For the Implementation Maturity characteristic for the standards and implementation specifications, ONC plans to publish a link, where available, to published maturity assessments based on known published criteria. Please help identify any publications that are publicly available and provide the hypertext links to those resources.
   No comment.

4. For the Adoption Level characteristic for the standards and implementation specifications, ONC plans to publish reference annotations or links to publicly available documentation known about adoption levels for listed standards. Please help identify any publications that are publicly available and provide the hypertext links to those resources.
   No comment.

5. For the Test Tool Availability characteristic for the standards and implementation specifications, ONC plans to publish references, where available, a to the publicly available test tool. Please help identify any publicly available test tools.
   No comment.

Section I: Vocabulary/Code Set

6. Within the Section I tables, Value Sets have been selected to substitute for what otherwise references Security Patterns in Sections II and III. Please review and provide feedback on placement, accuracy and the completeness of the selected value sets.
   Kaiser Permanente recommends substituting the insertion in various places where Security Patterns are applicable.

7. For subsection I-D: Functional Status/Disability, the Health Information Technology Standards Committee recommends using SNOMED®/LOINC® observation paring for this interoperability need. Do you support this approach?
   Kaiser Permanente supports this approach.

8. For subsection I-H: Industry and Occupation, there continues to be varied opinion on the standards or implementation specifications to be sited in these areas. Please review and provide feedback on what should be included and/or whether these areas should be removed.
   No comment.

9. For subsection I-R: Sexual Orientation and Gender Identity, Interoperability Need: Representing patient sex (at birth), what are the appropriate genetic identifiers or gender determinants (e.g., gonadal sex, karyotype sex) for potential inclusion in the ISA.
   No comment.

10. For subsection I-S: Social Determinants please help identify the adoption level of LOINC® for each of the Interoperability Needs.
    No comment.

11. Are there additional psychosocial Interoperability Needs with corresponding standards that should be included in the ISA?
    No comment.

12. For subsection I-T: Tobacco Use (Smoking Status), because of the current limitations, what surveys, instruments or tools are being used to collect tobacco use information that is more complete that the current coding methodologies?
    No comment.

Section II: Content / Structure

13. For the existing interoperability need, "representing clinical health information as a resource", public comments expressed this may not be the best language to describe this area. Please provide feedback on whether this is correct or recommend alternative language that better describes this interoperability need.
    FHIR resources are conceptual models of common entities used to describe items of interest in the healthcare domain. FHIR resources are structured such that they can be constrained or expanded to accommodate the needs of specific use cases. Clinically useful descriptions and definitions are much more specific for utility within specialized

knowledge domains, for example, vocabulary specific to a specialized medical domain – pathology of liver cell cancers. Another way of expressing this is that base FHIR resources are too unconstrained to be useful in conveying meaningful clinical information.

14. Opinions vary in the way (messaging vs. transport) the ISA should represent FHIR. Please review and provide feedback on the manner FHIR should be represented.

    FHIR resources are conceptual containers of commonly useful notions found in the field of healthcare, for example, patient or provider. The resources are designed in such a manner that their content can be expanded or constrained to satisfy use cases that manifest different levels of granularity. For example, an observation of blood pressure could be simply expressed as systolic and diastolic pressure readings or elaborated on to include much more detailed information such as laterality of the measurement, body position at the time of measurement. As to how the information in a resource, or resources, is exchanged, FHIR is intended to support several messaging styles – RESTful, transactional messaging (V2 like), exchange of documents (CDA like) and be useful in a service oriented context (Enterprise Service Bus).

    However, the team developing FHIR has emphasized the RESTful exchange paradigm over the other messaging styles. This has led to the development of what could be described as FHIR RESTful services that allow for various operations on FHIR resources found on conformant FHIR servers. To support such operations, the FHIR team has created what might be described as auxiliary resources that purposely support operations on resources found on conformant FHIR servers. Hence, the confusion over whether FHIR supports content or transport, or both. Despite the close association of FHIR with the RESTful style of messaging, even to the point of developing a FHIR RESTful sub-genre, FHIR resources in themselves do allow exchange of health-related content in several messaging styles.

Appendix I: Sources of Security Standards

15. Are there other authoritative sources for Security Standards that should be included in Appendix I?

    HL7 Healthcare Privacy and Security Classification System (HCS), Release 1
    Category: Privacy and Consent
    Description: The HCS enables interoperable exchange of security metadata by access control systems via automated labeling and segmentation of protected health information to ensure that only authorized users access this information.
    http://www.hl7.org/implement/standards/product_brief.cfm?product_id=345

    This is required/referenced in DS4P and should be included in the table format for Interoperability Need: Representing privacy and security classification of healthcare information.

HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1
Category: Privacy and Consent
Description: Creates constraints to standards for Meaningful Use consistent with federal and state privacy policies. Enables the exchange of protected/sensitive personal health information. Supports secure exchange of health information and privacy annotations applied to documents, messages, or atomic data elements.
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=354

HL7 Implementation Guide for CDA®, Release 2: Consent Directives, Release 1
Category: Privacy and Consent
Description: Enables interoperable and computable consents expressed as structured HL7 privacy and security vocabulary, BPPC, and XACML policies. This standard is the only specification available for encoding consent rules that can be enforced by data segmentation. It enables an interoperable "glide path," for trading partners at various levels of maturity to support patient preferences as end user develop capabilities to consume and computably enforce consent directives. The only available means for automating the generation and consumption of patient consent directives in CDA based exchanges is to use the HL7 Consent Directive CDA IG.
HL7 Implementation Guide for CDA®, Release 2: Consent Directives, Release 1 http://www.hl7.org/implement/standards/product_brief.cfm?product_id=280

Digital Authentication Guideline, Special Publication 800-63-3, Public Draft, Q4 2016. https://www.nist.gov/itl/nstic/special-publication-800-63-3 [NOTE: Substantial update 800-63-3—although in public comment period, this is more relevant than that of 800-63-2].

Framework for Improving Critical Infrastructure Cybersecurity, V1, February 2014. https://www.nist.gov/sites/default/files/documents/cyberframework/cybersecurity-framework-021214.pdf

Guide for Conducting Risk Assessments, Special Publication 800-30 Revision 1, September 2012.
http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-30r1.pdf [NOTE: Publication sited without the publication name]

Because data can flow between mobile devices and PHR or EHR, it is important to explore security and privacy issues associated with the consumer mobile context.

OASIS and other security related standards were mentioned in public comments, but not specifically addressed in the final 2016 Advisory. This may be resolved as the security patterns are filled out. OASIS, and related standards, should be included in Appendix II

Privacy involves what to protect and security dictates how to protect it. Thus, Kaiser Permanente recommends renaming this section to "Sources of Security and Privacy Standards" to be consistent with several of the standards currently denoted.

Lastly, since HIPAA requires the Secretary of Health and Human Services to adopt standards developed by ANSI-accredited standards developers ("ASDs") whenever possible, providing a link to the ASDs may be beneficial. Many of these are now embedded in the standard/ implementation specification sections of the document.

Conclusion

Kaiser Permanente hopes the comments and recommendations will help contribute to a stronger, more practical, realistic and achievable version of the 2017 Advisory. Thank you for considering our comments. Please contact me (510-271-5639; email: jamie.ferguson@kp.org) or Lori Potter (510-271-6621; email lori.potter@kp.org) with any questions or concerns.

Sincerely,

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